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November 8, 1977

. . . The telephone rang about nine- [it was] Bill Rutter (Professor of Biochemistry, UCSF) telling me that the Somatostatin experiments (by H. Boyer in his department) were now "all o.k. with the University, a matter of some "sloppy paperwork" having accounted for the earlier reports that no permission had been granted by the Institutional Review Board for the tour-de-force of programming E.Coli to make this small peptide. The plasmid contained an artificial gene for β -galactosidase-Met-Somatostatin ¹. Thus the protein product had no biological activity (somatostatin having no Met, yet it could be easily split with cyanogen bromide. No Memorandum of Understanding (MUA) had been sent to NIH because Genentech "had paid for it by contract", yet there was this little matter of no MUA being completed and filed with the local IRB . . .

The hearings were held in Dirkson 5110, a room that was new to me, with its sail boats, model train, and other toys of commerce in a case on one wall. The chairman, Senator Adlai Stevenson III, had sent an excellent letter of invitation, in which sensible question followed sensible question, no tricks; indeed his orientation was my own, no proposal of excessive

¹Hall, Stephen S., Invisible Frontiers, the Race to Synthesize a Human Gene, 1987, Atlantic Monthly Press, New York.

legislation like that contained in S 1217 or HR 7897--the bills which had innocently begun in our Interagency Committee and then grown malignant by the ambitions of Ted Kennedy or the well-meant excesses of the House Committee.

With Stevenson was the Senator-Astronaut, Harrison Schmitt from New Mexico, an engineer who was a staunch apologist for science and forgiver of the sins of the practitioners yet his friendly asides today would not be enough to save us from Adlai's utterly fair, persistent, legal briefs that edged slowly, persistently into the damning facts of the 'California Caper'. The 'crime', mind you, was not Boyer's somatostatin, but Rutter's cloning of the insulin gene using a pBR320, an uncertified E.Coli vector. How to explain the slow discovery of this--or the fast discovery and slow reaction, which ended in the destruction of the clones and then the beginning all over again in with another vector in April ²? Or the mysterious months of delay in telling the IRB at UCSF? The inadequate report of the IRB to NIH and our learning about this only because Wade called us from Science--all this was what Adlai wanted to know.

The hearing began calmly enough, with Frank Press, the President's Science Advisor, accompanied by his Deputy, Gil Omenn, as the first witnesses. Hardly off to a start, both veered off the road onto a soft shoulder and began talking about an "Administration Bill" and about other alternatives. Frank invited me to sit with them and I soon found myself answering

² Cf Nicholas Wade in Science, October, 1977.

some of the questions thrown to them. I noticed the Chairman's eyebrows indicating that he wished I had not accepted Press' invitation. I got much more uncomfortable as I heard the Science Advisor plumping for legislation and suggesting that the answers were all there in that "Administration Bill". Is it possible he didn't realize the good version of that bill was dead and replaced by new bills far less benign? Frank had to leave and was accorded a "thank you" from the Chairman that was less than effusive.

My turn next, I began reading from those few spots in my prepared testimony that did not already lie at the feet of the stenographer shredded by previous testimony. As I went over the reasons why we rejected a regulatory agency role for NIH, Senator Stevenson began to sigh. This sign of unrest was soon followed by gathering storm of questions about certification of plasmids, including the exact wording in new and proposed guidelines concerning this process. Then he pursued with me intimate details of the UCSF story, details I had not mastered for this hearing. . . I had determined not to try to excuse NIH at this hearing, emphasizing that we were "going to demand a full report from UCSF about a story that however painful, had not resulted in any serious biological consequences, only "injury to administrative process." We would never be able, and were determined not to respond like a regulatory agency. Gartland with his staff of one, usually keeping no records of telephone calls, Hans Stetten forgetting until October that he had a

telephone call [from Rutter] about some plasmid in March, etc. , and all the rest of the innocent peccadillo. We all knew instinctively that statutes or regulations would not work to govern laboratory science. Now, however, we will be plagued for our innocent assumptions, for thousands of hours of painful meetings, the creation of the EIS, the thoughtful poring over version after version of new guidelines, the necessity of keeping calm in the face of the hysterical and the exploitative, and accepting the cries of scientists who hate all these processes. Is all of this going to be for nothing because of one uncertified plasmid?

Our appearance is held up by a whistle-stop appearance by Margaret Mead, stick-in-hand, her fine head bowed over a hastily-prepared and confusing text. . . a grand old scold railing away at "too much research," "too little research", "a world in danger", but exactly from what we are not sure. We return to the stand, Omenn still hanging with me.

I . . . know that someone must take the heat for the revealed misbehaviors in the university. It will have to be the NIH Director. . . The Senators fuss with their notes, and one-by-one the sailboats in the case appear to capsize in the rising wind. My diary will later record the rambling thoughts at the time, overblown phrases to the effect that this is the worst hour of "proximal self-governance". . . and the "voluntary self-policing role of science".

We finally are released about 12:30. The staff who remained

later told how Rutter and Boyer, in their turn, were taken through a step-by-step account of what they had done. ³ Sen. Stevenson's final admonition to them made clear that if this brings regulation and laws, gentlemen, your actions will have brought this upon all of your peers.

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I make several resolves after this, the most hostile and embarrassing hearing I have had so far. One is not to be driven by depression into smoking again. A second is to deal with the heads of the universities on MUA's and the similar matters on which rested the survival of the guidelines. Scientist-to-scientist understanding has led to a near defeat. We shall have to sharpen implementation in the revised guidelines due in December. And we either must have some kind of benign preemptive law in 6 months, or we will have to abandon this attempt to devise self-regulation. It's vain to place all hope in the behavior of scientists. ⁴

November 20.

Yesterday, Vic Cohn wrote a piece for the Post based on the EIS. ⁵It was, for him, a fair piece leaving the readers with a

³ Rutter felt that he had poorly treated by the Stevenson Committee and expresses his feelings in a letter dated 11.22.77 to Chairman Adlai Stevenson III [attached].

⁴ See attached memo from DSF to the record, dated 11/16/77, summarizing discussions within the Assembly of Life Sciences, NAS, on alleged violation of NIH Guidelines for rDNA research.

⁵ Article by Victor Cohn entitled "NIH Sees a 'Small' Risk in Gene Work", appearing in the November 18, 1977 edition of The Washington Post. [attached].

sense that NIH was acting responsibly, if a bit deliberately, (considering that over a year has been spent in wrangling over the revisions. At last the EIS is out, available for Justice to use in defending us against the Friends of the Earth (the second circuit court in N. Y. C.) and Mack in Frederick, MD.

There were some interesting events after the Stevenson hearings. Philip Handler's public testimony before Stevenson adopted the Quixote-stance of a First Amendment privilege for science. [I had publically jettisoned this wistful theme earlier before an audience of scientists at Columbia⁶, only a few diehards like Gerhard Piel ever defend it anymore in public.] Then in camera Handler went before the Executive Committee of Life Sciences to urge them to write a resolution demanding NIH to make a full inquiry of UCSF. Robert Berliner telephoned and Norton Zinder came by later to tell me how close the Committee had come to passing such a resolution. They had also queried Hans Stetten at the meeting. Hans had sought my opinion, and I urged them not to take such action, because, while NIH might find it comfortable to make a spectacle of UCSF at demand of the Academy, it would then be too easy for Senator Kennedy's staff or other hawks to use the NAS declaration to have a public inquisition, with a resulting mass auto-de-fe of Boyer, NIH and voluntarism. Of course, Page 60 the anomalous NAS position of "no-law-is-needed, but take-the-

⁶ Fredrickson, D.S. The public governance of science. Man and Medicine 3: 77-88, 1978.

grants-away-from-the-rascals" is an untenable one. We will have to find a gentler way to achieve uniformity and one way is to get tougher in our revisions. Yesterday Halvor Halvorsen sat across the 'Rembrandt Table' in my office. Hal was seeking the shadow of a window bar to keep the bright sun from his blue Scandinavian eyes. His scruffy beard meets sideburns, giving him a somewhat seedy look, yet like someone out of an Ibsen drama. Hal is ambitious to play a national role in this recombinant madness, and he has been very effective this year. He's steadfastly stood up for reasonable legislation, and I agree with him.

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I think we must get Burke Zimmerman to rake through the ashes of bills previously drafted to learn if Paul Rogers will back an appropriate kind of bill. Maybe we could get Harley Staggers [Chairman of the House Interstate Commerce Committee of which Rogers Health Committee is a part] with him. We should try the Senate route (even with Kennedy?). Rogers was at NIH on Monday. I brought him to my office and, over coffee, we chatted about centers. I did not raise the issues of Guidelines or statutes. This weekend I had to turn to a paper on science funding --grants to centers--where there is a mounting need for answers to some other complex problems.